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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,090	10/14/2007	Octavian Schatz	BOH06278P00220US	7674
38939	7590	12/23/2009	EXAMINER	
DYKEMA GOSSETT PLLC			CHUNDURU, SURYAPRABHA	
10 S. WACKER DR., STE. 2300				
CHICAGO, IL 60606			ART UNIT	PAPER NUMBER
			1637	
			MAIL DATE	DELIVERY MODE
			12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/587,090	SCHATZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suryapraba Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 October 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-13 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>1/30/08</u> .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Status of Application***

1. Claims 1-13 are pending. Claims 14-67 are cancelled by the Preliminary Amendment filed on July 21, 2006.

***Priority***

2. This application filed on October 14, 2007 is a 371 of PCT/EP05/00620 filed on 1/22/05 which claims foreign priority to EPO 04001462.3 filed on 1/23/04. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO 04001462.3 on 1/23/04. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

***Information Disclosure Statement***

3. The Information Disclosure Statement filed on January 30, 2008 has been considered and acknowledged.

***Objection to the Abstract of the Disclosure***

4. The abstract of the disclosure is objected to because

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed

150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The instant abstract comprises more than 150 words.

Correction is required. See MPEP § 608.01(b).

### ***Informalities***

5. The following informalities are noted:

- (i) Claim 11 recites 'avidine, streptavidine, extravidine'. Typo error. It should have been 'avidin, streptavidin, extravidin'.
- (ii) For the arrangement of the specification, consideration of the guidelines in MPEP 601 is suggested.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, step d) recites the limitation "the first type II restriction enzyme" in line 1 of step d). There is insufficient antecedent basis for this limitation in the claim. The preceding step b) recites 'a first type IIS restriction enzyme' and the limitation in step d) lacks support in

the preceding step b) and results in lack of antecedent basis for said limitation. Amendment to recite ‘the type IIS restriction enzyme’ obviates the rejection. Further claim 2 recites ‘the long single-stranded overhang, which lacks support in the preceding claim 1 upon which the instant claim depends since the first ligation product of claim 1, step c) does not recite that the first ligation product comprises a long single stranded overhang.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Schatz et al. (EP 1 411 122 A1).

Schatz et al. teach a method for manufacturing of a nucleic acid molecule of claim 1, comprising

- a) providing a first at least partially double stranded oligonucleotide comprising a first and a second single stranded overhang (see Fig. 1, abstract of the disclosure, page 4, paragraph 0010, step a));
- b) providing a second at least partially double stranded oligonucleotide that comprises a first type IIS restriction enzyme recognition site and a modification that allows the oligonucleotide to be coupled to a surface and a single stranded overhang (see Fig. 1, abstract, page 4, paragraph 0010, step b));
- c) ligating the first and the second oligonucleotides via the single strand overhangs to form a first ligation product (see Fig. 1, abstract, page 4, paragraph 0010, step c));
- d) cutting the first ligation product with the type IIS restriction enzyme releasing an elongated first partially double stranded oligonucleotide having a first and second single strand overhang and a truncated second partially double-stranded oligonucleotide (see Fig.1, abstract, page 4, paragraph 0010, step e));
- e) immobilizing the truncated second partially double-stranded oligonucleotide, the unreacted second partially double-stranded oligonucleotide and/or uncut first ligation product via the modification to a surface (Fig. 1, abstract, page 4, paragraph 0010, step f)-g));
- f) repeating steps a) to e) (see page 4, paragraph 0010, step i)).

With regard to claim 2-3, Schatz et al. teach that the first ligation product is immobilized via the long single-strand overhang (see page 4, paragraph 0010, page 9, paragraph 0034).

With regard to claim 4, Schatz et al. teach that the method comprises washing the immobilized first ligation product and separating it from the surface (see page 21, paragraph 0078).

With regard to claim 5-7, Schatz et al. teach that the first overhang comprises a length of 1, 2, 3, 4, 5, 6 or 7 nucleotides and the first and second overhangs of the first oligonucleotide allows stable hybridization (see page 5, paragraph 0013-0014, page 12, paragraph 0044).

With regard to claim 8, Schatz et al. teach that the single stranded overhang comprises 5 nucleotides (see page 5, paragraph 0014).

With regard to claim 9-11, Schatz et al. teach that the modification is biotin modification and interaction with the support occurs via biotin modification and the interaction group comprises streptavidin (see page 12, paragraph 0044, page 14, paragraph 0048).

With regard to claim 12, Schatz et al. teach that a part of nucleic acid to be manufactured is part of the elongated first partially double stranded oligonucleotide (see Fig. 1, page 1, paragraph 0010, page 14, paragraph 0050).

With regard to claim 13, Schatz et al. teach that the steps a) to e) are repeated at least once and the nucleotides transferred from the second and any partially double stranded oligonucleotides provided in step b) to the first oligonucleotide are the nucleic acid to be manufactured or part thereof (see page 14, paragraph 0050, page 15, paragraph 0054). Accordingly the claims are anticipated.

B. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz (WO 00/75368 A2) (US2006/0115850A1 is herein used as an English translation of the patent WO 00/75368).

Schatz teaches a method for manufacturing of a nucleic acid molecule of claim 1, comprising

- a) providing a first at least partially double stranded oligonucleotide comprising a first and a second single stranded overhang (anchor oligo) (see Fig. 1, page 1, paragraph 0007, page 4, paragraphs 0075-0076);
- b) providing a second at least partially double stranded oligonucleotide that comprises a first type IIS restriction enzyme recognition site and a modification that allows the oligonucleotide to be coupled to a surface and a single stranded overhang (splinker oligo) (see Fig. 1, page 1, paragraph 0008-0009, page 4, paragraphs 0077-0079);
- c) ligating the first and the second oligonucleotides via the single strand overhangs to form a first ligation product (see Fig. 1, page 1, paragraph 0010, page 5, paragraph 0080);
- d) cutting the first ligation product with the type IIS restriction enzyme releasing an elongated first partially double stranded oligonucleotide having a first and second single strand overhang and a truncated second partially double-stranded oligonucleotide (see Fig.1, page 1, paragraph 0012-0018);
- e) immobilizing the truncated second partially double-stranded oligonucleotide, the unreacted second partially double-stranded oligonucleotide and/or uncut first ligation product via the modification to a surface (Fig. 1, page 1, 0019 indicating second oligonucleotide immobilized to a solid surface in step b, also see page 2, paragraph 0027 coupling of oligonucleotides through modification to a solid support);
- f) repeating steps a) to e) (see page 1, paragraph 0020).

With regard to claim 2-3, Schatz teaches that the first ligation product is immobilized via the long single-strand overhang (see page 2, paragraph 0027).

With regard to claim 4, Schatz teaches that the method comprises washing the immobilized first ligation product and separating it from the surface (see page 1, paragraph 0011, 0014, 0019).

With regard to claim 5-7, Schatz teaches that the first overhang comprises a length of 1, 2, 3, 4, or 5 nucleotides and the first and second overhangs of the first oligonucleotide allows stable hybridization (see page 2, paragraph 0027, page 5, paragraph 0082).

With regard to claim 8, Schatz teaches that the single stranded overhang comprises 5 nucleotides (see page 5, paragraph 0082).

With regard to claim 9-11, Schatz teaches that the modification is biotin modification and interaction with the support occurs via biotin modification and the interaction group comprises streptavidin (see page 2, paragraph 0027).

With regard to claim 12, Schatz teaches that a part of nucleic acid to be manufactured is part of the elongated first partially double stranded oligonucleotide (see Fig. 1, page 1, paragraph 0010, page 5, paragraph 0080).

With regard to claim 13, Schatz teaches that the steps a) to e) are repeated at least once and the nucleotides transferred from the second and any partially double stranded oligonucleotides provided in step b) to the first oligonucleotide are the nucleic acid to be manufactured or part thereof (see page 1, paragraph 0020). Accordingly the claims are anticipated.

C. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Schatz et al. (US 2006/0194202 A1).

Schatz et al. teach a method for manufacturing of a nucleic acid molecule of claim 1, comprising

- a) providing a first at least partially double stranded oligonucleotide comprising a first and a second single stranded overhang (see page 2, paragraph 0032);
- b) providing a second at least partially double stranded oligonucleotide that comprises a first type IIS restriction enzyme recognition site and a modification that allows the oligonucleotide to be coupled to a surface and a single stranded overhang (see page 2, paragraph 0033);
- c) ligating the first and the second oligonucleotides via the single strand overhangs to form a first ligation product (see page 2, paragraph 0034);
- d) cutting the first ligation product with the type IIS restriction enzyme releasing an elongated first partially double stranded oligonucleotide having a first and second single strand overhang and a truncated second partially double-stranded oligonucleotide (see page 2, paragraph 0035);
- e) immobilizing the truncated second partially double-stranded oligonucleotide, the unreacted second partially double-stranded oligonucleotide and/or uncut first ligation product via the modification to a surface (page 2, paragraph 0036);
- f) repeating steps a) to e) (see page 3, paragraph 0040).

With regard to claim 2-3, Schatz et al. teach that the first ligation product is immobilized via the long single-strand overhang (see page 9, paragraph 0136).

With regard to claim 4, Schatz et al. teach that the method comprises washing the immobilized first ligation product and separating it from the surface (see page 15, paragraph 0178).

With regard to claim 5-8, Schatz et al. teach that the first overhang comprises a length of 1, 2, 3, 4, 5, 6 or 7 nucleotides and the first and second overhangs of the first oligonucleotide allows stable hybridization (see page 3, paragraph 0042).

With regard to claim 9-11, Schatz et al. teach that the modification is biotin modification and interaction with the support occurs via biotin modification and the interaction group comprises streptavidin (see page 9, paragraph 0136).

With regard to claim 12, Schatz et al. teach that a part of nucleic acid to be manufactured is part of the elongated first partially double stranded oligonucleotide (see page 9, paragraph 0138).

With regard to claim 13, Schatz et al. teach that the steps a) to e) are repeated at least once and the nucleotides transferred from the second and any partially double stranded oligonucleotides provided in step b) to the first oligonucleotide are the nucleic acid to be manufactured or part thereof (see page 9, paragraph 0138). Accordingly the claims are anticipated.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

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